

REMARKS

I. Status Of The Claims And The Rejections

This application originally included 24 claims. Applicant previously withdrew claims 18-24 in response to a Restriction Requirement.

Of the remaining claims 1-17, claims 1-16 were rejected for alleged lack of novelty under Section 102(e), based on U.S. Patent No. 6,629,982, issued to Day et. al. ("Day '982"). Claim 17 was rejected for alleged obviousness under Section 103, based also on Day '982.

Applicant respectfully traverses the rejections and requests reconsideration of the patentability of the claims, for the reasons described below. Nonetheless, for the purpose of clarifying the subject matter regarded as patentable, applicant has amended independent claim 1, and has also added new claims 25-30.

II. The Scope And Content Of The Prior Art / Day '982

Day '982 discloses a three pin skull clamp with load distribution indicators on the rocker arm side of the clamp. More particularly, Fig 1 shows a skull clamp 10 with a C-shaped frame. One end of the frame holds a single pin assembly 22 aligned along an axis 20. At the opposite end of the C-shape, a rotatable rocker arm holds a pair of spaced rocker arm skull pins 30.

For each of the rocker arm skull pins 30, a pin carrier assembly 50, shown in more detail in Figs 3 and 4 of Day '982, includes an indicator cap 66 with parallel markings 72 to provide a visual indication of the engagement force from the head 18 of the patient to the pin 30. This force is transferred via an internal piston 56 of the pin carrier assembly 50.

As shown in Figs 3 and 4 of Day '982, when the tips 32 of the skull pin 30 engage the head of a patient, the force is transferred along the opposite ends 35 thereof to an enlarged head 57 of an internal piston 56. A flathead screw 64 holds an outer end of the piston 56, via a threaded hole 59. The enlarged head 57 typically urges the skull pin 30 in the direction of the patient, due to the force of an internal spring 58. More particularly, one end of the internal spring 58 contacts the enlarged head 57 of the piston 56, while an opposite end of the internal spring 58 engages an internal surface 70 of the adjustment screw 54.

As described therein, the purpose of Day '982 is to enable the neurosurgeon and operating room attendants to achieve equal force distribution for the spaced skull pins 30 on the rocker arm side of the skull clamp. If the indicator caps 66 for the spaced pins 30 do not show equal force, then in a typical situation the operating room attendants will maneuver the rocker arm about axis 46 to achieve equal distribution of the engagement forces on the rocker arm side of the skull clamp.

Thus, the primary purpose of Day '982 is that of enabling the neurosurgeon and operating room attendants to compare the engagement forces of the spaced pins held by the rocker arm. And if an initial orientation of the patient relative to the skull clamp shows unequal forces of the spaced skull pins 30, then the rocker arm is adjusted to correct that situation, and thereby achieve substantially equal distribution forces. These principles are described via the following paragraph of Day '982:

The present invention is not designed to identify the specific amount of engagement force between the head 18 and each of the two pins 30 located on the rocker arm 44. The magnitude of the engagement forces on the single pin side of the skull clamp will be known, within a reasonable amount of certainty, and the force vectors for the pins 30 on the rocker arm 44 will, when combined, equal, i.e. counteract, the engagement

force from the single pin side. Thus, it is not necessary to know actual forces on the rocker arm pins. It is only necessary to assure that the engagement forces on the rocker arm pins are equally distributed, or at least sufficiently close to being equally distributed to provide secure holding of the head 18 of the patient during surgery.

Thus, the purpose of Day '982 is not force measurement or quantification. It is force comparison for the rocker arm skull pins, wherein the comparison enables the appropriate personnel to take steps to achieve equal load distribution.

III. Differences Between The Claims And Day '982

The present claims patentably define over Day '982, for a number of significant reasons. First of all, Day '982 focuses on comparing the forces of two spaced skull pins mounted on the rocker arm of a skull clamp. Day '982 does not focus on measuring or quantifying those skull pin forces. In fact, as noted above, Day '982 expressly states that it is not necessary to know the magnitude of the forces applied to the skull pins on the rocker arm. The focus of Day '982 is equalizing load distribution.

Although the structure of Day '982 could be used to move the rocker arm skull pins toward the head of the patient (via rotation of handle 52), the recessed end 35 of skull pin 30 of Day '982 must remain seated within the pin carrier assembly 50. Thus, Day '982 discloses only limited capability for moving the rocker arm skull pins 30 toward the head of the patient. Simply stated, Day '982 is not designed for significant movement of the skull pins 30 toward the head of the patient, for engagement therewith. Rather, engagement with the head of the patient occurs via movement of the single pin assembly 22.

Also, there is no teaching in Day '982 to use the indicators to movably adjust the force applied to the head of the patient on opposite sides of the patient's head. Rather, with Day '982 the

movement toward the patient's head to engage the head with the three skull pin occurs via the single pin assembly 22 shown on the left side of Fig 1.

Clearly, Day '982 differs from the present claims. Day '982 clearly does not support a lack of novelty rejection under Section 102(e), for any of the claims. Accordingly, applicant respectfully requests that this rejection be withdrawn.

This is especially true with respect to dependent claims 11-14, which refer to the lock nut which holds the skull pin assembly relative to the skull clamp. This lock nut is used to hold the position of the skull pin relative to the skull clamp after the pin load applicator has movably adjusted the force applied by the skull pin. There is absolutely no similar structure shown in Day '982.

Dependent claim 17 focuses on the radiolucent composition of the materials of the apparatus of claim 1. Contrary to assertions in the Office Action, claim 17 would not have been obvious in view of Day '982.

More specifically, the structure as shown and described in these Figures, with multiple adjustable skull pin assemblies which move relative to a skull clamp, is designed to optimize flexibility for accommodating various patient head sizes, and to do so within a limited volume so as to facilitate scanning of the patient, and scanning in a manner which does not produce undesired artifacts. Day '982 relates to comparing and adjusting a conventional three pin skull clamp, so that the forces on the rocker arm skull pins will be distributed evenly. Day '982 works for its intended purpose. The blanket suggestion in the Office Action to make the components of this invention radiolucent, shows a failure to appreciate the complexity of these devices, and also the seriousness of their purpose.

More particularly, these devices are used to hold the head of a patient during brain surgery. They can not slip inadvertently. Different materials are not easily interchangeable.

The Section 103 rejection of claim 17 is based solely on impermissible hindsight. Applicant respectfully asserts that it is improper and it should be withdrawn. The same is true with respect to added claim 26, which depends upon claim 17 but further recites an additional skull pin assembly with a corresponding skull pin.

Moreover, new claim 25 recites additional details of the knob used as part of the pin load applicator, which is a unitary component connectable to and disconnectable from the skull clamp as a single component.

Added claims 27-30 also patentably define over Day '982, for substantially the same reasons set forth above. None of the new claims, and none of the amendments to original claims, should raise any adverse issues under Section 112.

IV. The Present Claims Are Patentable

Applicant's acknowledge that a person of ordinary skill in the art, relative to these claims, would have knowledge of Day '982. In fact, applicant's assignee owns Day '982. Thus, applicant recognizes that Day '982 is the most relevant prior art. Clearly, Day '982 represented an advance in the technology of cranial stabilization devices which enabled neurosurgeons and operating room attendants to more easily and safely support the skull of a patient in a safe and uniform manner.

Nonetheless, the present claims represent the "next generation" with regard to the capability of skull pin applicators, wherein the skull pin applicator is removable, and is also better adapted for use with radiolucent head holding structure, wherein a smaller space envelope is required.

For all the reasons set forth above in the prior section, applicant respectfully asserts that the claims patentably define over Day '982. More specifically, applicant respectfully asserts that the alleged lack of novelty rejection of claims 1-16 is moot in view of the amendments to claim 1. Also, as for alleged obvious under Section 103, applicant respectfully asserts that there is no objective reason to modify Day '982 in the manner suggested, to achieve the subject matter recited by any of the claims. Only impermissible hindsight, based on a reading of this application, would lead one of ordinary skill in the art to modify Day '982 in the manner suggested. Thus, the rejection under Section 103 should also be withdrawn.

For these reasons, applicant respectfully asserts that the present claims are patentable, and requests that they be allowed without further delay.

If there are any questions regarding this paper, or which might otherwise further this case on to allowance, please contact the undersigned at (513) 241-2324. Moreover, if any other charges or credits are necessary to complete this communication, please apply them to Deposit Account 23-3000.

Respectfully submitted,



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